UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

MEMORANDUM

DATE: January 3, 2022

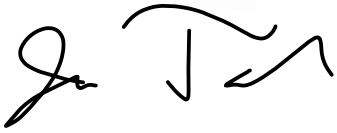
SUBJECT: Efficacy Review for:

CRB, EPA Reg No. 5813-120 (Primary),
Submission: 1072568, E-sub: 65707; 63160 Action Code Case: 00311988; 00300212

CRB I, EPA Reg No. 5813-121 (Secondary),
Submission: 1072664, E-sub: 65784, Action Code Case: 00313085

FROM: Atinuke Onyonyor
Efficacy Branch
Antimicrobials Division (7510P)
Date Signed: December 23, 2021

James Tauber, Ph.D., Microbiologist
Efficacy Branch
Antimicrobials Division (7510P)
Date Signed: December 30, 2021



THRU: Thao Pham
Efficacy Branch
Antimicrobials Division (7510P)
Date Signed: December 30, 2021

TO: Demson Fuller, PM 32 /Jack Hall/ Wanda Henson
Regulatory Management Branch I
Antimicrobials Division (7510P)

APPLICANT: The Clorox Co.
c/o PS&RC
P. O. Box 493
Pleasanton, CA 94566-0803

Formulation from the Label:
CRB, EPA Reg. No. 5813-120 (Primary)

Active Ingredient(s)	% by wt.
Sodium Hypochlorite	7.5%
Other Ingredients	92.5%
Total	100.0%

* Yields 7.17% available chlorine

CRB I, EPA Reg. No. 5813-121 (Secondary)

Active Ingredient(s)	% by wt.
Sodium Hypochlorite	7.55%
Other Ingredients	92.45%
Total	100.0%

* Yields 7.17% available chlorine

I BACKGROUND

Product Description (as packaged, as applied): Concentrated Liquid (Dilutable)

Submission type: Label Amendment

Currently registered efficacy claim(s): Disinfectant (bactericidal, virucidal, fungicidal, tuberculocidal, C. difficile sporicide), sanitizer (food contact, non-food contact, laundry)

Requested action(s): Registrant is requesting label amendments for CRB (EPA Reg. No. 5813-120) and CRB I (EPA Reg. No. 5813-121) and is relying on a combination of previously submitted and approved data, as well as 24 new efficacy studies (MRIDs 51631001 - 51631024) to support:

1. Addition of laundry pre-soak disinfection claims (applying data from previously accepted hard surface disinfection and sanitization claims)
2. Addition of laundry disinfection claims (citing data from Clorox Bleach EPA Reg. No. 5813-1 and Ultra Clorox Brand Regular Bleach 5813-50)
3. Addition of dilution options for hard surface disinfection (applying data from MRIDs 51631001 – 51631024)
4. Addition of disinfection claims against three SARS-CoV-2 variants on hard, non-porous surfaces

Documents considered in this review:

- Cover letter from applicant to EPA
  - CRB, EPA Reg. No. 5813-120 dated 5/4/2021
  - CRB, EPA Reg. No. 5813-120 dated 7/20/2021
  - CRB I, EPA Reg. No. 5813-121 dated 7/21/2021
- Proposed label
  - CRB, EPA Reg. No. 5813-120 dated 7/16/2021
  - CRB I, EPA Reg. No. 5813-121 dated 7/15/2021
- Data Matrix (EPA Form 8570-35)
  - CRB, EPA Reg. No. 5813-120 dated 7/20/2021
  - CRB I, EPA Reg. No. 5813-121 dated 7/21/2021
- 25 efficacy studies (MRIDs 51631001 – 51631024 and MRID 51556901)
- 1 supplemental efficacy discussion (MRID 516310-25)
- Confidential Statement of Formula (EPA Form 8670-4)
  - CRB, EPA Reg. No. 5813-120 dated 8/9/2018
  - CRB I, EPA Reg. No. 5813-121dated 8/27/2018
- AD Efficacy Review for CRB, EPA Reg. No. 5813-120 and CRB I, EPA Reg. No. 5813-121; DP Barcode: 458766; E-sub: 52763 dated 9/15/2020
- Efficacy Review for CRB, EPA Reg No. 5813-120; DP Barcode: 455278; E-sub: 43668, Revised 5/1/2020
- Efficacy Review for CRB, EPA File Symbol 5813-REN; DP Barcode 449098; E-sub: 449098; Dated 5/19/2019

II PROPOSED DIRECTIONS FOR USE

General Disinfection Directions for Use [For] Disinfecting:
-or-
To disinfect hard, nonporous surfaces ***insert use surface(s) from Table 1*** -and/or- ***insert surface material(s) from Table 3***

Must either use "Pre-wash surface." ***within directions,*** or add "For visibly soiled surfaces, preclean surfaces before disinfecting." ***at the end of directions***. Mix 1/3 cup of this product -or- bleach per 1 gal[lon] water. [To disinfect ***insert surface(s) from Table 1*** -and/or- ***insert surface material(s) from Table 3***,] [pre-wash surface] mop or wipe with bleach solution. Let stand -or- Allow solution to contact surface for [at least] 6 min[utes]. Rinse well and air dry. [For visibly soiled surfaces, preclean surfaces before disinfecting.]
-or-

1. Mix 1/3 cup this product -or- bleach per 1 gal[lon] water. [Pre-wash surface -or- item.]
2. Apply, let stand 6 min[utes]
3. Rinse, [and] air dry. [For visibly soiled surfaces, preclean surfaces before disinfecting.]

[For] Toilet Bowls -and/or- bidets:
Flush toilet -and/or- Bidet. Pour 1/3 cup of this product into bowl. Brush entire bowl including rim with a scrub brush or mop. Let stand 6 min[utes] before flushing again.

[For] Potty Seats -or- Trainers:
Empty seat -and/or- pre-wash surface. Fill with 1/3 cup of this product per gal[lon] of water. Let stand 6 min[utes]. Rinse and air dry.

[For] Litter Boxes:
Remove litter. Wash box in soap and water. Fill with 1/3 cup of this product per gal[lon] of water. Let stand 6 min[utes]. Rinse and air dry.

Must remove brackets if either Feline Parvovirus or Canine Parvovirus is listed on the label. [For Feline Parvovirus -and/or- Canine Parvovirus
use 1/2 cup of this product per 1 gal[lon] of water. Let stand for 10 min[utes].]

[For] Mold and Mildew:
Must either use "Pre-wash surface." ***within directions***, or add "For visibly soiled surfaces, preclean surfaces before disinfecting." ***at the end of directions***. Mix 1/3 cup of this product -or- bleach per 1 gal[lon] water. [To disinfect ***insert surface(s) from Table 1*** -and/or- ***insert surface material(s) from Table 3***,] [pre-wash surface] mop or wipe with bleach solution. Let stand -or- Allow solution to contact surface for [at least] 10 min[utes]. Rinse well and air dry. [For visibly soiled surfaces, preclean surfaces before disinfecting.]

For] [Laundry, Cleaning and] Disinfecting -or- To [Clean and] Disinfect [Laundry]
Laundry -and/or- Bleachable Fabrics -and/or- dishcloths -and/or- rags
1 cup [8 fl oz]: Standard Machine
1.] Sort laundry by color. [2.] Add detergent. [3.] Add 1 cup bleach to wash water. [4.] Add clothes -and/or- dishcloths -and/or- rags [and start wash]. Ensure contact with bleach [solution] for 10 min[utes]. -or- Follow the laundry use directions using 1 cup of bleach -or- this product. Ensure contact with bleach [solution] for 10 min[utes]. [Avoid bleaching wool, silk, mohair, leather, spandex and non-fast colors. Use [with] a detergent.]

[For] Presoak Disinfection -and-or- to Disinfect [Laundry]
Laundry -and/or- Bleachable Fabrics -and/or- dishcloths -and/or- rags
1/3 cup [2.7 fl oz]: 1 gallon
Submerge laundry -or- clothes -and/or- dishcloths -and/or- rags -and/or- fabric completely and soak items for 6 min[utes]. Rinse [thoroughly] or machine wash as directed. [No detergent required.]

III STUDY SUMMARIES

1.	**MRID**	516310-01					
Study Objective		Disinfectant - bactericidal					
Study Title		AOAC Use-Dilution Method					
Testing Lab, Lab Study ID		Accuratus Lab Services; A26108					
Experimental Start Date		8/29/2018		**Study Completion Date:**	10/09/2018		
Test organism(s) **☒ 1 ☐ 2 ☐ 3 ☐ 4+**		*Pseudomonas aeruginosa* (ATCC 15442) 1 mL culture inoculated					
Test Method		AOAC Use-Dilution Method Protocol No. CX18081018.UD.1 *(copy provided)*					
Application Method		Liquid					
Test Substance Preparation	**Name/ID**	CRB, FIS2018.0136; 5813-120 and CRB I, FIS2018.0139; 5813-121					
	Lots **☒ 1 ☐ 2 ☐ 3**	18DEJ02 (5.69% sodium hypochlorite)					
	Preparation	Tested Concentration: LCL Tested Dilution: 1:52.84; prepared to a NaOCl concentration of 1173 ppm by combining 19.7 mL test substance + 1021.3 mL of 100 ppm AOAC Synthetic Hard Water					
Soil load		5% Fetal Bovine Serum					
Carrier type, # per lot		Stainless steel penicylinders, 60 carriers/batch					
Test conditions		**Contact time**	5 minutes 30 seconds	**Temp**	20˚C	**RH**	--
Neutralizer		10 mL Letheen Broth + 0.1% Sodium Thiosulfate					
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, etc.)		No protocol amendments No listed protocol deviations					

2.	**MRID**	516310-02					
Study Objective		Disinfectant – bactericidal					
Study Title		AOAC Use-Dilution Method					
Testing Lab, Lab Study ID		Accuratus Lab Services, A26109					
Experimental Start Date		8/31/2018		**Study Completion Date**	10/9/2018		
Test organism(s) **☒ 1 ☐ 2 ☐ 3 ☐ 4+**		*Pseudomonas aeruginosa* (ATCC 15442) 1 mL culture inoculated					
Test Method		AOAC Use-Dilution Method Protocol No. CX18081018.UD.2 *(copy provided)*					
Application Method		Liquid					
Test Substance Preparation	**Name/ID**	CRB, FIS2018.0136; 5813-120 and CRB I, FIS2018.0139; 5813-121					
	Lots **☒ 1 ☐ 2 ☐ 3**	18DEJ03 (5.68% sodium hypochlorite)					
	Preparation	Tested Concentration: LCL Tested Dilution: 1:52.08; prepared to a NaOCl concentration of 1164 ppm by combining 19.7 mL test substance + 1006.3 mL of 100 ppm AOAC Synthetic Hard Water					
Soil load		5% Fetal Bovine Serum					
Carrier type, # per lot		Stainless steel penicylinders, 60 carriers/lot					
Test conditions		**Contact time**	5 minutes 30 seconds	**Temp**	20˚C	**RH**	--

Neutralizer	10 mL Letheen Broth + 0.1% Sodium Thiosulfate
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, etc.)	No protocol amendments No listed protocol deviations

3.	**MRID**	516310-03					
Study Objective		Disinfectant - bactericidal					
Study Title		AOAC Use-Dilution Method					
Testing Lab, Lab Study ID		Accuratus Lab Services, A26110					
Experimental Start Date		9/4/2018	**Study Completion Date:**			10/9/2018	
Test organism(s) **☒ 1 ☐ 2 ☐ 3 ☐ 4+**		*Pseudomonas aeruginosa* ATCC 15442 1 mL culture inoculated					
Test Method		AOAC Use-Dilution Method Protocol No. CX18081018.UD.3 *(copy provided)*					
Application Method		Liquid					
Test Substance Preparation	**Name/ID**	CRB, FIS2018.0136; 5813-120 and CRB I, FIS2018.0139; 5813-121					
	Lots **☒ 1 ☐ 2 ☐ 3**	18DEJ04 (5.69% sodium hypochlorite)					
	Preparation	Tested Concentration: LCL Tested Dilution: 1:52.58; prepared to a NaOCl concentration of 1168 ppm by combining 19.7 mL test substance + 1016.3 mL of 100 ppm AOAC Synthetic Hard Water					
Soil load		5% Fetal Bovine Serum					
Carrier type, # per lot		Stainless steel penicylinders, 60 carriers/lot					
Test conditions		**Contact time**	5 minutes 30 seconds	**Temp**	20˚C	**RH**	--
Neutralizer		10 mL Letheen Broth + 0.1% Sodium Thiosulfate					
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, etc.)		No protocol amendments No listed protocol deviations					

4.	**MRID**	516310-04		
Study Objective		Disinfectant – bactericidal		
Study Title		AOAC Use-Dilution Method		
Testing Lab, Lab Study ID		Accuratus Lab Services, A25576		
Experimental Start Date		6/1/2018	**Study Completion Date:**	09/06/2018
Test organism(s) **☒ 1 ☐ 2 ☐ 3 ☐ 4+**		*Bordetella pertussis* ATCC 12743 1 mL culture inoculated		
Test Method		AOAC Use-Dilution Method Protocol No. CX18041018.UD.1 *(copy provided)*		
Application Method		Liquid		
Test Substance Preparation	**Name/ID**	CRB, FIS2018.0136; 5813-120 and CRB I, FIS2018.0139; 5813-121		
	Lots **☐ 1 ☒ 2 ☐ 3**	18DEJ03 (5.68% sodium hypochlorite) 18DEJ04 (5.69% sodium hypochlorite)		
	Preparation	Tested Concentration: LCL Tested Dilution: 1:49; prepared using 15.77 mL of the test substance and 757.0 mL of 100 ppm AOAC Synthetic Hard Water.		

Soil load	5% Fetal Bovine Serum					
Carrier type, # per lot	Stainless steel penicylinders, 10 carriers/lot					
Test conditions	**Contact time**	5 minutes 30 seconds	**Temp**	21˚C	**RH**	--
Neutralizer	10 mL Letheen Broth + 0.1% Sodium Thiosulfate					
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, etc.)	Protocol Amendments: Per Sponsor's request, the protocol is being amended to change the Sponsor from Annette Angus to Nipa Modi in Annette's absence. Protocol Deviation: During testing on 6/1/18, the drying temperature when the carriers were put in the incubator was 37.6˚C. Per the protocol, the drying temperature should be 35-37˚C. This deviation had no impact on the overall intent of the protocol. Population controls demonstrated acceptable results, thereby establishing no significant effects of the elevated drying temperature.					

5.	**MRID**	516310-05				
Study Objective		Disinfectant - bactericidal				
Study Title		AOAC Use-Dilution Method				
Testing Lab, Lab Study ID		Accuratus Lab Services; A25577				
Experimental Start Date		5/29/2018	**Study Completion Date:**	09/07/2018		
Test organism(s) **☒ 1 ☐ 2 ☐ 3 ☐ 4+**		*Campylobacter jejuni* ATCC 29428 1 mL culture inoculated				
Test Method		AOAC Use-Dilution Method Protocol No. CX18041018.UD.2 *(copy provided)*				
Application Method		Liquid				
Test Substance Preparation	**Name/ID**	CRB, FIS2018.0136; 5813-120 and CRB I, FIS2018.0139; 5813-121				
	Lots **☐ 1 ☒ 2 ☐ 3**	18DEJ03 (5.68% sodium hypochlorite) 18DEJ04 (5.69% sodium hypochlorite)				
	Preparation	Tested Concentration: LCL Tested Dilution: 1:49; prepared using 3.15 mL of the test substance and 151.40 mL of 100 ppm AOAC Synthetic Hard Water				
Soil load		5% Fetal Bovine Serum				
Carrier type, # per lot		Stainless steel penicylinders, 10 carriers/lot				
Test conditions		**Contact time**	5 minutes 30 seconds	**Temp**	20˚C	**RH**	--
Neutralizer		10 mL Letheen Broth + 0.1% Sodium Thiosulfate				
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, etc.)		Protocol Amendments: Per Sponsor's request, the protocol is being amended to change the Sponsor from Annette Angus to Nipa Modi in Annette's absence. No listed protocol deviation				

6.	**MRID**	516310-06		
Study Objective		Disinfectant – bactericidal		
Study Title		AOAC Use-Dilution Test		
Testing Lab, Lab Study ID		Microbac Laboratories, Inc., 320-743		
Experimental Start Date		5/29/2018	**Study Completion Date:**	10/3/2018
Test organism(s) **☒ 1 ☐ 2 ☐ 3 ☐ 4+**		*Listeria monocytogenes* ATCC 19111 1 mL culture inoculated		
Test Method		AOAC Use-Dilution Method		

		Protocol No. 320.1.05.09.18 *(copy provided)*					
Application Method		Liquid					
Test Substance Preparation	**Name/ID**	CRB, FIS2018.0136; 5813-120 and CRB I, FIS2018.0139; 5813-121					
	Lots ☐ 1 ☒ 2 ☐ 3	18DEJ03 (5.68% sodium hypochlorite) 18DEJ04 (5.69% sodium hypochlorite)					
	Preparation	Tested Concentration: LCL Tested Dilution: 1:48.99 prepared using 19.715 mL of concentrate was diluted in 946.25 mL of 100 ppm ± 2.9% AOAC Hard Water					
Soil load		5% Heat-inactivated Fetal Bovine Serum					
Carrier type, # per lot		Stainless steel penicylinders, 10 carriers/lot					
Test conditions		**Contact time**	5 minutes 30 seconds	**Temp**	21˚C	**RH**	52-53%
Neutralizer		10 mL Letheen Broth + 0.2% Sodium Thiosulfate					
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, etc.)		Protocol Amendments: 1. The Sterility, Neutralizer Effectiveness, and Viability and Purity control sections of the Protocol state that the Tryptic Soy Agar (TSA) will be used. This is an error and should state that Brain Heart Infusion Agar (BHIA) will be utilized for all controls. 2. Project Sheet No. 1 states that the confirmation plates are incubated for 24 ± 2 hours. This is an error and should state, as per Protocol, that all confirmation plates will be incubated for 48 ± 2 hours. 3. At the request of the Sponsor, the Contact person of the study is changed from Annette Angus to Nipa Modi. Protocol Deviations: 1. According to the Protocol, the carrier counts range must fall between $1.0x10^4$ and $1.0x10^5$ CFU/carrier. The average counts for this study exceeded the maximum limit. However, since the performance standard was achieved, the quality and integrity of the study are not negatively affected, and the test does not need to be repeated.					

7.	**MRID**	516310-07					
Study Objective		Disinfectant – bactericidal					
Study Title		AOAC Use-Dilution Method					
Testing Lab, Lab Study ID		Accuratus Lab Services, A25585					
Experimental Start Date		5/31/2018	**Study Completion Date:**		09/10/2018		
Test organism(s) ☒ 1 ☐ 2 ☐ 3 ☐ 4+		Multi-Drug Resistant (MDR) *Acinetobacter baumanni* ATCC 19606 1 mL culture inoculated					
Test Method		AOAC Use-Dilution Method Protocol No. CX18041018.UD.11 *(copy provided)*					
Application Method		Liquid					
Test Substance Preparation	**Name/ID**	CRB, FIS2018.0136; 5813-120 and CRB I, FIS2018.0139; 5813-121					
	Lots ☐ 1 ☒ 2 ☐ 3	18DEJ03 (5.68% sodium hypochlorite) 18DEJ04 (5.69% sodium hypochlorite)					
	Preparation	Tested Concentration: LCL Tested Dilution: 1:49 prepared using 15.77 mL of the test substance and 757.0 mL of 100 ppm AOAC Synthetic Hard Water.					
Soil load		5% Fetal Bovine Serum					
Carrier type, # per lot		Stainless steel penicylinders, 10 carriers/lot					
Test conditions		**Contact time**	5 minutes 30 seconds	**Temp**	20˚C	**RH**	--

Neutralizer	10 mL Letheen Broth + 0.1% Sodium Thiosulfate
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, etc.)	Protocol Amendments: 1. At the request of the Sponsor, the Contact person of the study is changed from Annette Angus to Nipa Modi. No listed protocol deviations Antibiotic sensitivity testing was performed using a representative culture from the day of testing and verified the antibiotic resistance pattern of the test organism.

8.	**MRID**	516310-08				
Study Objective		Disinfectant – bactericidal				
Study Title		AOAC Use-Dilution Method				
Testing Lab, Lab Study ID		Accuratus Lab Services, A25561				
Experimental Start Date		5/25/2018	**Study Completion Date:**	10/03/2018		
Test organism(s) **☒ 1 ☐ 2 ☐ 3 ☐ 4+**		*Shigella dysenteriae* ATCC 11835 1 mL culture inoculated				
Test Method		AOAC Use-Dilution Method Protocol No. CX18041018.UD.14 *(copy provided)*				
Application Method		Liquid				
Test Substance Preparation	**Name/ID**	CRB, FIS2018.0136; 5813-120 and CRB I, FIS2018.0139; 5813-121				
	Lots **☐ 1 ☒ 2 ☐ 3**	18DEJ03 (5.68% sodium hypochlorite) 18DEJ04 (5.69% sodium hypochlorite)				
	Preparation	Tested Concentration: LCL Tested Dilution: 1:48.9; prepared using 13.15 mL of the test substance and 630.83 mL of 100 ppm AOAC Synthetic Hard Water				
Soil load		5% Fetal Bovine Serum				
Carrier type, # per lot		Stainless steel penicylinders, 10 carriers/lot				
Test conditions		**Contact time**	5 minutes 30 seconds	**Temp**	20˚C	**RH**	--
Neutralizer		10 mL Letheen Broth + 0.1% Sodium Thiosulfate				
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, etc.)		Protocol Amendment: 1. Protocol is amended to change Study Directors due to the departure of the original Study Director from Accuratus Lab Services. The Study Director has been changed from Andrea Epperly to Jamie Herzan. 2. At the request of the Sponsor, the protocol is being amended to change the Sponsor from Annette Angus to Nipa Modi in Annette's absence. No listed protocol deviations				

9.	**MRID**	516310-09		
Study Objective		Disinfectant - bactericidal		
Study Title		AOAC Use-Dilution Method		
Testing Lab, Lab Study ID		Accuratus Lab Services, A26042		
Experimental Start Date		8/13/2018	**Study Completion Date:**	10/16/2018
Test organism(s) **☒ 1 ☐ 2 ☐ 3 ☐ 4+**		*Streptococcus pneumoniae* ATCC 6305 1 mL culture inoculated		
Test Method		AOAC Use-Dilution Method Protocol No. CX18072618.UD.3 *(copy provided)*		

Application Method		Liquid					
Test Substance Preparation	**Name/ID**	CRB, FIS2018.0136; 5813-120 and CRB I, FIS2018.0139; 5813-121					
	Lots ☐ 1 ☒ 2 ☐ 3	18DEJ03 (5.68% sodium hypochlorite) 18DEJ04 (5.69% sodium hypochlorite)					
	Preparation	Tested Concentration: LCL Tested Dilution: 1:48.9; prepared using 11.27 mL of the test substance and 540.71 mL of 100 ppm AOAC Synthetic Hard Water					
Soil load		5% Fetal Bovine Serum					
Carrier type, # per lot		Stainless steel penicylinders, 10 carriers/lot					
Test conditions		**Contact time**	6 minutes	**Temp**	20˚C	**RH**	--
Neutralizer		10 mL Brain Heart Infusion Broth + 0.1% Sodium Thiosulfate (Primary); 10 mL Brain Heart Infusion Broth (Secondary)					
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, etc.)		Protocol Amendments: The protocol is amended to change Study Directors due to the departure of the original Study Director from Accuratus Lab Services. The Study Director has been changed from Carrie Bauer to Thomas Breyen. No listed protocol deviations					

10.	**MRID**	516310-10					
Study Objective		Disinfectant – bactericidal					
Study Title		AOAC Use-Dilution Method					
Testing Lab, Lab Study ID		Accuratus Lab Services, A25563					
Experimental Study Date:		6/1/2018	**Study Completion Date:**		10/3/2018		
Test organism(s) ☒ 1 ☐ 2 ☐ 3 ☐ 4+		Vancomycin Resistant *Enterococcus faecalis* -VRE (ATCC 51299) 1 mL culture inoculated					
Test Method		AOAC Use-Dilution Method Protocol No. CX18041018.UD.17 *(copy provided)*					
Application Method		Liquid					
Test Substance Preparation	**Name/ID**	CRB, FIS2018.0136; 5813-120 and CRB I, FIS2018.0139; 5813-121					
	Lots ☐ 1 ☒ 2 ☐ 3	18DEJ03 (5.68% sodium hypochlorite) 18DEJ04 (5.69% sodium hypochlorite)					
	Preparation	Tested Concentration: LCL Tested Dilution: 1:49; prepared using 15.77 mL of the test substance and 757.0 mL of 100 ppm AOAC Synthetic Hard Water.					
Soil load		5% Fetal Bovine Serum					
Carrier type, # per lot		Stainless steel penicylinders, 10 carriers/lot					
Test conditions		**Contact time**	5 minutes 30 seconds	**Temp**	21˚C	**RH**	--
Neutralizer		10 mL Letheen Broth + 0.1% Sodium Thiosulfate					
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, etc.)		Protocol Amendments: 1. The protocol is amended to change Study Directors due to the departure of the original Study Director from Accuratus Lab Services. The Study Director has been changed from Andrea Epperly to Jamie Herzan. 2. Per the Sponsor's request, the protocol is being amended to change the Sponsor from Annette Angus to Nipa Modi in Annette's absence. No listed protocol deviations					

	Antibiotic sensitivity testing was performed using a representative culture from the day of testing and verified the antibiotic resistance pattern of the test organism.

11.	**MRID**	516310-11					
Study Objective		Disinfectant - bactericidal					
Study Title		AOAC Use-Dilution Method					
Testing Lab, Lab Study ID		Accuratus Lab Services, A25571					
Experimental Start Date		6/1/2018	**Study Completion Date:**	10/04/18			
Test organism(s) **☒ 1 ☐ 2 ☐ 3 ☐ 4+**		*Vibrio cholerae* ATCC 11623 1 mL culture inoculated					
Test Method		AOAC Use-Dilution Method Protocol No. CX18041018.UD.18 *(copy provided)*					
Application Method		Liquid					
Test Substance Preparation	**Name/ID**	CRB, FIS2018.0136; 5813-120 and CRB I, FIS2018.0139; 5813-121					
	Lots **☐ 1 ☒ 2 ☐ 3**	18DEJ03 (5.68% sodium hypochlorite) 18DEJ04 (5.69% sodium hypochlorite)					
	Preparation	Tested Concentration: LCL Tested Dilution: 1:49; prepared using 15.77 mL of test substance and 757.0 mL of 100 ppm AOAC Synthetic Hard Water.					
Soil load		5% Fetal Bovine Serum					
Carrier type, # per lot		Stainless steel penicylinders, 10 carriers/lot					
Test conditions		**Contact time**	5 minutes 30 seconds	**Temp**	20˚C	**RH**	
Neutralizer		10 mL Letheen Broth + 0.1% Sodium Thiosulfate					
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, etc.)		Protocol Amendments: 1. The protocol is amended to change Study Directors due to the departure of the original Study Director from Accuratus Lab Services. The Study Director has been changed from Andrea Epperly to Jamie Herzan. 2. Per the Sponsor's request, the protocol is being amended to change the Sponsor from Annette Angus to Nipa Modi in Annette's absence. No listed protocol deviations					

12.	**MRID**	516310-12		
Study Objective		Disinfectant - bactericidal		
Study Title		AOAC Use-Dilution Method		
Testing Lab, Lab Study ID		Accuratus Lab Services, A25587		
Experimental Start Date		6/1/2018	**Study Completion Date:**	09/06/2018
Test organism(s) **☒ 1 ☐ 2 ☐ 3 ☐ 4+**		*Yersinia enterocolitica* ATCC 23715 1 mL culture inoculated		
Test Method		AOAC Use-Dilution Method Protocol No. CX18041018.UD.19 *(copy provided)*		
Application Method		Liquid		
Test Substance Preparation	**Name/ID**	CRB, FIS2018.0136; 5813-120 and CRB I, FIS2018.0139; 5813-121		
	Lots **☐ 1 ☒ 2 ☐ 3**	18DEJ03 (5.68% sodium hypochlorite) 18DEJ04 (5.69% sodium hypochlorite)		
	Preparation	Tested Concentration: LCL		

		Tested Dilution: 1:49; prepared using 15.77 mL of test substance and 757.0 mL of 100 ppm AOAC Synthetic Hard Water.					
Soil load		5% Fetal Bovine Serum					
Carrier type, # per lot		Stainless steel penicylinders, 10 carriers/lot					
Test conditions		**Contact time**	5 minutes 30 seconds	**Temp**	20˚C	**RH**	--
Neutralizer		10 mL Letheen Broth + 0.1% Sodium Thiosulfate					
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, etc.)		Protocol Amendments: 1. At the request of the Sponsor, the protocol is being amended to change the Sponsor from Annette Angus to Nipa Modi in Annette's absence. No listed protocol deviations					

13.	**MRID**	516310-13			
Study Objective		Disinfectant – fungicidal			
Study Title		Fungicidal Use-Dilution Method			
Testing Lab; Lab Study ID		Accuratus Lab Services; A25546			
Experimental Start Date		5/25/2018	**Study Completion Date:**	10/09/2018	
Test organism(s) **☒ 1 ☐ 2 ☐ 3 ☐ 4+**		*Candida albicans* ATCC 10231 1 mL culture inoculated			
Test Method		Fungicidal Use Dilution Method Protocol # CX18041018.FUD.2 *(copy provided)*			
Application Method		Liquid			
Test Substance Preparation	**Name/ID**	CRB, FIS2018.0136; 5813-120 and CRB I, FIS2018.0139; 5813-121			
	Lots **☐ 1 ☒ 2 ☐ 3**	18DEJ03 (5.68% sodium hypochlorite) 18DEJ04 (5.69% sodium hypochlorite)			
	Preparation	Tested Concentration: LCL Tested Dilution: 1:48.97; prepared using 13.15 mL of the test substance and 630.83 mL of 100 ppm AOAC Synthetic Hard Water			
Soil load		5% Fetal Bovine Serum (FBS)			
Carrier type, # per lot		Stainless steel penicylinders, 10 carriers/lot			
Test conditions		**Contact time**	9 minutes 30 seconds	**Temp**	20°C
Neutralizer		10 mL Sabouraud Dextrose Broth + 0.07% Lecithin + 0.5% Tween 80 (Primary and Secondary)			
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, etc.)		Protocol Amendments: 1. At the request of the Sponsor, the protocol is being amended to change the Sponsor from Annette Angus to Nipa Modi in Annette's absence. No listed protocol deviations			

14.	**MRID**	516310-14		
Study Objective		Disinfectant – fungicidal		
Study Title		Fungicidal Use-Dilution Method		
Testing Lab; Lab Study ID		Accuratus Lab Services; A25547		
Experimental Start Date		5/25/2018	**Study Completion Date:**	10/09/2018
Test organism(s) **☒ 1 ☐ 2 ☐ 3 ☐ 4+**		*Trichophyton interdigitale* ATCC 9533 1 mL culture inoculated		
Test Method		Fungicidal Use-Dilution Method Protocol # CX18041018.FUD.1 *(copy provided)*		
Application Method		Liquid		

Test Substance Preparation	**Name/ID**	CRB, FIS2018.0136; 5813-120 and CRB I, FIS2018.0139; 5813-121					
	Lots ☐ 1 ☒ 2 ☐ 3	18DEJ03 (5.68% sodium hypochlorite) 18DEJ04 (5.69% sodium hypochlorite)					
	Preparation	Tested Concentration: LCL Tested Dilution: 1:48.97; prepared using 13.15 mL of the test substance and 630.83 mL of 100 ppm AOAC Synthetic Hard Water					
Soil load		5% Fetal Bovine Serum (FBS)					
Carrier type, # per lot		Stainless steel penicylinders, 10 carriers/lot					
Test conditions		**Contact time**	9 minutes 30 seconds	**Temp**	20°C	**RH**	--
Neutralizer		10 mL Sabouraud Dextrose Broth with 0.1% Sodium Thiosulfate (Primary); Sabouraud Dextrose Broth (Secondary)					
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, etc.)		Protocol Amendments: 1. At the request of the Sponsor, the protocol is being amended to change the Sponsor from Annette Angus to Nipa Modi in Annette's absence. No listed protocol deviations					

15.	**MRID**	516310-15					
Study Objective		Disinfectant - virucidal					
Study Title		Virucidal Hard-Surface Efficacy Test – Adenovirus Type 2					
Testing Lab; Lab Study ID		Microbac Laboratories, Inc.; 320-738					
Experimental Start Date		5/15/2018	**Study Completion Date:**		11/08/2018		
Test organism(s) ☒ 1 ☐ 2 ☐ 3 ☐ 4+		Adenovirus Type 2, Strain: Adenoid 6, ATCC VR-846 1 mL culture inoculated					
Indicator Cell Culture		A549 cells, ATCC CCL-185					
Test Method		ASTM E1053-11 Virucidal Hard-Surface Efficacy Test Protocol # 320.4.04.04.18 *(copy provided)*					
Application Method		Liquid					
Test Substance Preparation	**Name/ID**	CRB, FIS2018.0136; 5813-120 and CRB I, FIS2018.0139; 5813-121					
	Lots ☐ 1 ☒ 2 ☐ 3	18DEJ03 (5.68% sodium hypochlorite) 18DEJ04 (5.69% sodium hypochlorite)					
	Preparation	Tested Concentration: LCL Tested Dilution: 1:48.97; prepared using 3.943 mL test substance and 189.25 mL of 100 ppm AOAC Synthetic Hard Water					
Soil load		5% Fetal Bovine Serum (FBS)					
Carrier type, # per lot		Glass Petri dishes, 1 carrier/lot					
Test conditions		**Contact time**	5 minutes 30 seconds	**Temp**	21°C	**RH**	60.8-60.9%
Neutralizer		Dulbecco's Modified Eagle Medium (DMEM) + 10% FBS + 0.5% Polysorbate 80 + 2% HEPES + 0.5% $Na_2S_2O_3$ + 0.025N HCl					
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, etc.)		No protocol amendments No listed protocol deviations					

16.	**MRID**	516310-16		
Study Objective		Disinfectant - virucidal		
Study Title		Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces		
Testing Lab; Lab Study ID		Accuratus Lab Services; A25477		
Experimental Start Date		5/23/2018	**Study Completion Date:**	09/06/2018

Test organism(s) **☒ 1 ☐ 2 ☐ 3 ☐ 4+**		Coxsackievirus type B3, Strain: Nancy ATCC VR-30 0.2 mL culture inoculated					
Indicator Cell Culture		BGMK (Buffalo Green monkey kidney) cells originally obtained from Diagnostic Hybrids Inc.					
Test Method		ASTM E1053-11 Virucidal Hard-Surface Efficacy Test Protocol # CX18041018.COX *(copy provided)*					
Application Method		Liquid					
Test Substance Preparation	**Name/ID**	CRB, FIS2018.0136; 5813-120 and CRB I, FIS2018.0139; 5813-121					
	Lots **☐ 1 ☒ 2 ☐ 3**	18DEJ03 (5.68% sodium hypochlorite) 18DEJ04 (5.69% sodium hypochlorite)					
	Preparation	Tested Concentration: LCL Tested Dilution: 1:48.9; prepared using 1.00 mL test substance and 47.99 mL gallon 100 ppm AOAC Synthetic Hard Water					
Soil load		5% Fetal Bovine Serum (FBS)					
Carrier type, # per lot		Glass Petri dishes, 1 carrier/lot					
Test conditions		**Contact time**	5 minutes 30 seconds	**Temp**	20°C	**RH**	--
Neutralizer		Sephadex Gel Filtration Columns					
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, etc.)		Protocol Amendments: 1. At the request of the Sponsor, the protocol is being amended to change the Sponsor from Annette Angus to Nipa Modi in Annette's absence. No listed protocol deviations					

17.	**MRID**	516310-17					
Study Objective		Disinfectant - virucidal					
Study Title		Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces					
Testing Lab; Lab Study ID		Accuratus Lab Services; A25453					
Experimental Start Date		5/24/2018	**Study Completion Date:**	09/11/2018			
Test organism(s) **☒ 1 ☐ 2 ☐ 3 ☐ 4+**		Enterovirus type D68, Strain US/KY/14-18953 ATCC VR-1825 0.2 mL culture inoculated					
Indicator Cell Culture		Human rhabdomyosarcoma (RD) cells ATCC CCL-136					
Test Method		ASTM E1053-11 Virucidal Hard-Surface Efficacy Test Protocol # CX18041018.ENTV *(copy provided)*					
Application Method		Liquid					
Test Substance Preparation	**Name/ID**	CRB, FIS2018.0136; 5813-120 and CRB I, FIS2018.0139; 5813-121					
	Lots **☐ 1 ☒ 2 ☐ 3**	18DEJ03 (5.68% sodium hypochlorite) 18DEJ04 (5.69% sodium hypochlorite)					
	Preparation	Tested Concentration: LCL Tested Dilution: 1:48.9; prepared using 1.00 mL test substance and 47.99 mL gallon 100 ppm AOAC Synthetic Hard Water					
Soil load		5% Fetal Bovine Serum (FBS)					
Carrier type, # per lot		Glass Petri dishes, 1 carrier/lot					
Test conditions		**Contact time**	5 minutes 30 seconds	**Temp**	22°C	**RH**	--
Neutralizer		Sephadex Gel Filtration Columns					
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, etc.)		Protocol Amendments: 1. At the request of the Sponsor, the protocol is being amended to change the Sponsor from Annette Angus to Nipa Modi in Annette's absence. No listed protocol deviations					

18.	**MRID**	516310-18					
Study Objective		Disinfectant - virucidal					
Study Title		Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces					
Testing Lab; Lab Study ID		Accuratus Lab Services; A25450					
Experimental Start Date		5/17/2018	**Study Completion Date:**	09/11/2018			
Test organism(s) **☒ 1 ☐ 2 ☐ 3 ☐ 4+**		Hepatitis A virus, Strain: HM-175, Source: AppTec Laboratory Services 0.2 mL virus inoculated					
Indicator Cell Culture		FRhK-4 (fetal Rhesus monkey kidney) cells ATCC CRL-1688					
Test Method		ASTM E1053-11 Virucidal Hard-Surface Efficacy Test Protocol # CX18041018.HAV *(copy provided)*					
Application Method		Liquid					
Test Substance Preparation	**Name/ID**	CRB, FIS2018.0136; 5813-120 and CRB I, FIS2018.0139; 5813-121					
	Lots **☐ 1 ☒ 2 ☐ 3**	18DEJ03 (5.68% sodium hypochlorite) 18DEJ04 (5.69% sodium hypochlorite)					
	Preparation	Tested Concentration: LCL Tested Dilution: 1:48.9; prepared using 1.00 mL test substance and 47.99 mL of 100 ppm AOAC Synthetic Hard Water					
Soil load		5% Fetal Bovine Serum (FBS)					
Carrier type, # per lot		Glass Petri dishes, 1 carrier/lot					
Test conditions		**Contact time**	5 minutes 30 seconds	**Temp**	20°C	**RH**	--
Neutralizer		Sephadex Gel Filtration Columns					
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, etc.)		Protocol Amendments: 1. At the request of the Sponsor, the protocol is being amended to change the Sponsor from Annette Angus to Nipa Modi in Annette's absence. No listed protocol deviations					

19.	**MRID**	516310-19					
Study Objective		Disinfectant - virucidal					
Study Title		Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces					
Testing Lab; Lab Study ID		Accuratus Lab Services; A25491					
Experimental Start Date		5/29/2018	**Study Completion Date:**	09/11/2018			
Test organism(s) **☒ 1 ☐ 2 ☐ 3 ☐ 4+**		Herpes simplex virus type 1, Strain: F (1) ATCC VR-733 0.2 mL virus inoculated					
Indicator Cell Culture		Vero cells, ATCC CCL-81					
Test Method		ASTM E1053-11 Virucidal Hard-Surface Efficacy Test Protocol # CX18041018.HSV1 *(copy provided)*					
Application Method		Liquid					
Test Substance Preparation	**Name/ID**	CRB, FIS2018.0136; 5813-120 and CRB I, FIS2018.0139; 5813-121					
	Lots **☐ 1 ☒ 2 ☐ 3**	18DEJ03 (5.68% sodium hypochlorite) 18DEJ04 (5.69% sodium hypochlorite)					
	Preparation	Tested Concentration: LCL Tested Dilution: 1:48.9; prepared using 1.00 mL test substance and 47.99 mL of 100 ppm AOAC Synthetic Hard Water					
Soil load		5% Fetal Bovine Serum (FBS)					
Carrier type, # per lot		Glass Petri dishes, 1 carrier/lot					
Test conditions		**Contact time**	5 minutes 30 seconds	**Temp**	20°C	**RH**	--

Neutralizer	Sephadex Gel Filtration Columns
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, etc.)	Protocol Amendments: 1. At the request of the Sponsor, the protocol is being amended to change the Sponsor from Annette Angus to Nipa Modi in Annette's absence. No listed protocol deviations

20.	**MRID**	516310-20				
Study Objective		Disinfectant - virucidal				
Study Title		Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces				
Testing Lab; Lab Study ID		Accuratus Lab Services; A25479				
Experimental Start Date		5/29/2018	**Study Completion Date:**	09/11/2018		
Test organism(s) **☒ 1 ☐ 2 ☐ 3 ☐ 4+**		Herpes simplex virus type 2, Strain: G (ATCC VR-734) 0.2 mL virus inoculated				
Indicator Cell Culture		Vero cells, ATCC CCL-81				
Test Method		ASTM E1053-11 Virucidal Hard-Surface Efficacy Test Protocol # CX18041018.HSV2 *(copy provided)*				
Application Method		Liquid				
Test Substance Preparation	**Name/ID**	CRB, FIS2018.0136; 5813-120 and CRB I, FIS2018.0139; 5813-121				
	Lots **☐ 1 ☒ 2 ☐ 3**	18DEJ03 (5.68% sodium hypochlorite) 18DEJ04 (5.69% sodium hypochlorite)				
	Preparation	Tested Concentration: LCL Tested Dilution: 1:48.9; prepared using 1.00 mL test substance and 47.99 mL of 100 ppm AOAC Synthetic Hard Water				
Soil load		5% Fetal Bovine Serum (FBS)				
Carrier type, # per lot		Glass Petri dishes, 1 carrier/lot				
Test conditions		**Contact time**	5 minutes 30 seconds	**Temp**	20°C	**RH**	--
Neutralizer		Sephadex Gel Filtration Columns				
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, etc.)		Protocol Amendments: 1. At the request of the Sponsor, the protocol is being amended to change the Sponsor from Annette Angus to Nipa Modi in Annette's absence. No listed protocol deviations				

21.	**MRID**	516310-21		
Study Objective		Disinfectant - virucidal		
Study Title		Virucidal Hard-Surface Efficacy Test - Middle East Respiratory Syndrome Coronavirus (MERS-CoV)		
Testing Lab; Lab Study ID		Microbac Laboratories, Inc.; 320-742		
Experimental Start Date		5/10/2018	**Study Completion Date:**	11/29/2018
Test organism(s) **☒ 1 ☐ 2 ☐ 3 ☐ 4+**		Middle East Respiratory Syndrome Coronavirus (MERS-CoV), Strain: EMC/2012, Source: BEI Resources (NR-44260) 0.4 mL virus inoculated		
Indicator Cell Culture		Vero E6 cells, ATCC CRL-1586		
Test Method		ASTM E1053-11 Virucidal Hard-Surface Efficacy Test Protocol # 320.8.04.04.18 *(copy provided)*		
Application Method		Liquid		
Test Substance Preparation	**Name/ID**	CRB, FIS2018.0136; 5813-120 and CRB I, FIS2018.0139; 5813-121		
	Lots **☐ 1 ☒ 2 ☐ 3**	18DEJ03 (5.68% sodium hypochlorite) 18DEJ04 (5.69% sodium hypochlorite)		

	Preparation	Tested Concentration: LCL Tested Dilution: 1:48.9; prepared using 7.886 mL test substance and 378.5 mL of 100 ppm AOAC Synthetic Hard Water					
Soil load		5% Fetal Bovine Serum (FBS)					
Carrier type, # per lot		Glass Petri dishes, 1 carrier/lot					
Test conditions		**Contact time**	5 minutes 30 seconds	**Temp**	20°C	**RH**	45.6- 46.3%
Neutralizer		2.0 mL Minimum Essential Medium + 10% FBS + 0.5% Polysorbate 80 + 2% HEPES + 0.5% $Na_2S_2O_3$ + 0.025N HCl.					
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, etc.)		Protocol amendment: 1. Protocol listed throughout study incorrectly as # 320.7.04.04.18. No listed protocol deviations					

22.	**MRID**	516310-22			
Study Objective		Disinfectant – virucidal			
Study Title		Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces			
Testing Lab; Lab Study ID		Accuratus Lab Services; Project # A25489			
Experimental Start Date		6/5/2018	**Study Completion Date**	9/10/2018	
Test organism(s) **☒ 1 ☐ 2 ☐ 3 ☐ 4+**		Murine Norovirus, Strain S99, Source: Friedrich-Loeffler-Institut, Insel Riems, Germany 0.2 mL virus inoculated			
Indicator Cell Culture		RAW 264.7 cells ATCC TIB-71			
Test Method		ASTM E1053-11 Virucidal Hard-Surface Efficacy Test Protocol # CX18041018.MNV *(copy provided)*			
Application Method		Liquid			
Test Substance Preparation	**Name/ID**	CRB, FIS2018.0136; 5813-120 and CRB I, FIS2018.0139; 5813-121			
	Lots **☐ 1 ☒ 2 ☐ 3**	18DEJ03 (5.68% sodium hypochlorite) 18DEJ04 (5.69% sodium hypochlorite)			
	Preparation	Tested Concentration: LCL Tested Dilution: 1:48.9; prepared using 1.00 mL test substance and 47.99 mL of 100 ppm AOAC Synthetic Hard Water			
Soil load		5% Fetal Bovine Serum (FBS)			
Carrier type, # per lot		Glass Petri dishes; 1 carrier/lot			
Test conditions		**Contact time**	5 minutes 30 seconds	**Temp**	20°C	**RH**	--
Neutralizer		Sephadex Gel Filtration Columns			
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, etc.)		Protocol Amendments: 1. At the request of the Sponsor, the protocol is being amended to change the Sponsor from Annette Angus to Nipa Modi in Annette's absence. No listed protocol deviations			

23.	**MRID**	516310-23		
Study Objective		Disinfectant – virucidal		
Study Title		Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces		
Testing Lab; Lab Study ID		Accuratus Lab Services; Project # A25454		
Experimental Start Date		5/24/2018	**Study Completion Date**	10/8/2018
Test organism(s) **☒ 1 ☐ 2 ☐ 3 ☐ 4+**		Respiratory syncytial virus (RSV), Strain Long ATCC VR-26 0.2 mL virus inoculated		

Indicator Cell Culture		Hep-2 (human larynx carcinoma) cells ATCC CCL-23					
Test Method		ASTM E1053-11 Virucidal Hard-Surface Efficacy Test Protocol # CX18041018.RSV *(copy provided)*					
Application Method		Liquid					
Test Substance Preparation	**Name/ID**	CRB, FIS2018.0136; 5813-120 and CRB I, FIS2018.0139; 5813-121					
	Lots **☐ 1 ☒ 2 ☐ 3**	18DEJ03 (5.68% sodium hypochlorite) 18DEJ04 (5.69% sodium hypochlorite)					
	Preparation	Tested Concentration: LCL Tested Dilution: 1:48.9; prepared using 1.00 mL test substance and 47.99 mL of 100 ppm AOAC Synthetic Hard Water					
Soil load		5% Fetal Bovine Serum (FBS)					
Carrier type, # per lot		Glass Petri dishes; 1 carrier/lot					
Test conditions		**Contact time**	5 minutes 30 seconds	**Temp**	20°C	**RH**	--
Neutralizer		Sephadex Gel Filtration Columns					
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, etc.)		Protocol Amendments: 1. At the request of the Sponsor, the protocol is being amended to change the Sponsor from Annette Angus to Nipa Modi in Annette's absence. No listed protocol deviations Initial assay performed 5/24/2018 was repeated on 6/28/2018 to recover at least 4 $\log_{10}$ of infectivity from dried virus control. Valid results were obtained from the assay performed on June 28, 2018.					

24.	**MRID**	516310-24					
Study Objective		Disinfectant – virucidal					
Study Title		Virucidal Hard-Surface Efficacy Test – SARS – Associated Coronavirus					
Testing Lab; Lab Study ID		Microbac Laboratories, Inc.; Project # 320-741					
Experimental Start Date		5/10/2018	**Study Completion Date**	11/29/2018			
Test organism(s) **☒ 1 ☐ 2 ☐ 3 ☐ 4+**		SARS-Associated Coronavirus, Strain: CDC 200300592, Source: ZeptoMetrix/CDC 0.4 mL virus inoculated					
Indicator Cell Culture		Vero E6 cells ATCC CRL-1586					
Test Method		ASTM E1053-11 Virucidal Hard-Surface Efficacy Test Protocol # 320.7.04.04.18 *(copy provided)*					
Application Method		Liquid					
Test Substance Preparation	**Name/ID**	CRB, FIS2018.0136; 5813-120 and CRB I, FIS2018.0139; 5813-121					
	Lots **☐ 1 ☒ 2 ☐ 3**	18DEJ03 (5.68% sodium hypochlorite) 18DEJ04 (5.69% sodium hypochlorite)					
	Preparation	Tested Concentration: LCL Tested Dilution: 1:48.9; prepared using 7.886 mL test substance and 378.5 mL of 100 ppm AOAC Synthetic Hard Water					
Soil load		5% Fetal Bovine Serum (FBS)					
Carrier type, # per lot		Glass Petri dishes, 1 carrier/lot					
Test conditions		**Contact time**	5 minutes 30 seconds	**Temp**	21°C	**RH**	40.0-46.0%
Neutralizer		Minimum Essential Medium + 10% FBS + 0.5% Polysorbate 80 + 2% HEPES + 0.5% $Na_2S_2O_3$ + 0.025N HCl.					
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, etc.)		No protocol amendments; No listed protocol deviations					

25.	**MRID**	515569-01					
Study Objective		Virucidal efficacy testing on hard, non-porous surface					
Study Title		A GLP Virucidal Efficacy Evaluation of a Liquid Hard Surface Disinfectant Substance Versus Variants of SARS-Related Coronavirus 2					
Testing Lab; Lab Study ID		Bioscience Laboratories, LLC.; 2102132-408F					
Experimental Start Date		03/25/2021	**Study Completion Date:**		04/27/2021		
Test organism(s) **☐ 1 ☐ 2 ☒ 3 ☐ 4+**		SARS-Related Coronavirus-2, isolates: 1) hCoV19/England/204820464/2020#NR-54000); 2) hCoV19/South Africa/KRISP-EC-K00532 l/2020 (BEI #NR-54008); 3) USA/CA_CDC_5574/2020 (BEI #NR 54011)					
Indicator Cell Culture		Vero E6 ATCC #CRL-1586 Passage 8 for strains 1 & 2; Passage 4 for strain 3					
Test Method		E1053-20; 810.2000; 810.2200					
Application Method		2.0 mL diluted product atop dried viral film					
Test Substance Preparation	**Name/ID**	CRB (5813-120) and CRB1 (5813-121)					
	Lots* **☐ 1 ☒ 2 ☐ 3**	21LMP04 (5.72% Sodium Hypochlorite; diluted to 1216.29 ppm) 21LMP05 (5.71% Sodium Hypochlorite; diluted to 1214.17 ppm) *According to the cover letter,"[a]s discussed with AD's Kristen Willis on February 17, 2021, efficacy testing was conducted utilizing 2 batches of product. Label changes are limited to these new claims."					
	Preparation	Tested concentration: LCL Tested Dilution: 10.4 ml into 519.4 ml water Diluent: 400 ppm AOAC synthetic hard water (actual: 414 and 393 ppm)					
Soil load		5% FBS					
Carrier type, # per lot		Glass petri dishes; 1 carrier/lot					
Test Conditions		**Contact Time**	5 minutes 30 seconds	**Temp**	21 - 22.0°C	**RH**	10 - 23.0%
Neutralizer		Dey-Engley (D/E) Neutralizing Broth.					
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, etc.)		The study director reports no protocol deviation. The study director reports one protocol amendment (correction of the product's name). The $TCID_{50}$/0.2 ml between the PRC and neutralization control not comparable. Per the lab's SOP (page 30), the neutralization control did not achieve 3 log_{10} $TCID_{50}$/ml.					

IV STUDY RESULTS

Bactericidal Efficacy					
MRID	**Organism**	**No. Exhibiting Growth/Total No. Tested**			**Average log_{10} CFU/Carrier**
		Batch 18DEJ02	**Batch 18DEJ03**	**Batch 18DEJ04**	
*Dilute 1/3 cup per gallon of 100 ppm hard water, 5% soil load, 5-minute 30 seconds contact time***					
516310-01	*Pseudomonas aeruginosa* ATCC 15442	0/60	--	--	6.70
516310-02		--	0/60	--	6.71
516310-03		--	--	0/60	7.10
516310-04	*Bordetella pertussis* ATCC 12743	--	0/10	0/10	6.43
516310-05	*Campylobacter jejuni* ATCC 129428	--	0/10	0/10	5.55
516310-06	*Listeria monocytogenes* ATCC 19111	--	0/10	0/10	5.3
516310-07	Multi-Drug Resistant (MDR) *Acinetobacter baumanni* ATCC 19606	--	0/10	0/10	4.39
516310-08	*Shigella dysenteria* ATCC 11835	--	0/10	0/10	4.87
516310-09	*Streptococcus pneumoniae*** ATCC 6305	--	1° = 0/10	1° = 0/10	4.50
			2° = 0/10	2° = 0/10	
516310-10	Vancomycin Resistant *Enterococcus faecalis* - VRE ATCC 51299	--	0/10	0/10	4.25
516310-11	*Vibrio cholerae* ATCC 11623	--	0/10	0/10	5.92
516310-12	*Yersinia enterocolitica* ATCC 23715	--	0/10	0/10	6.42

** Contact time of all organisms 5 minutes 30 seconds except for *Streptococcus pneumoniae* (MRID 516310-09) which the contact time is 6 minutes.
1°=Primary Subculture; 2°=Secondary Subculture

Fungicidal Efficacy					
MRID	**Organism**	**No. Exhibiting Growth/Total No. Tested**			**Average log_{10} CFU/Carrier**
		Batch 18DEJ02	**Batch 18DEJ03**	**Batch 18DEJ04**	
Dilute 1/3 cup per gallon of 100 ppm hard water, 5% soil load, 9-minute 30 seconds contact time					
516310-13	*Candida albicans* ATCC 10231	--	1° = 0/10	1° = 0/10	4.70
			2° = 0/10	2° = 0/10	
516310-14	*Trichophyton interdigitale* ATCC 9533	--	1° = 0/10	1° = 0/10	4.93
			2° = 0/10	2° = 0/10	

1°=Primary Subculture; 2°=Secondary Subculture

Virucidal Efficacy						
MRID	Organism	Description	Results			Dried Virus Control (Log_{10} $TCID_{50}$/carrier)
			Batch 18DEJ02	Batch 18DEJ03	Batch 18DEJ04	
Dilute 1/3 cup per gallon 100 ppm hard water, 5% soil load, 5-minute 30 seconds contact time						
516310-15	Adenovirus Type 2, Strain: Adenoid 6 Source: ATCC VR-846	Complete inactivation	--	10^{-2} to 10^{-7}	10^{-2} to 10^{-7}	7.10
		Cytotoxicity	--	No cytotoxicity	No cytotoxicity	
		Log_{10} $TCID_{50}$/carrier	--	≤ 1.10	≤ 1.10	
		Log Reduction	--	≥ 6.00	≥ 6.00	
516310-16	Coxsackievirus type B ATCC VR-30, Strain Nancy	Complete inactivation	--	10^{-1} to 10^{-8}	10^{-1} to 10^{-8}	8.00
		Cytotoxicity	--	No cytotoxicity	No cytotoxicity	
		Log_{10} $TCID_{50}$/carrier	--	≤ 0.50	≤ 0.50	
		Log Reduction	--	≥ 7.50	≥ 7.50	
516310-17	Enterovirus type D68, ATCC VR-1825, Strain US/KY/14-18953	Complete inactivation	--	10^{-1} to 10^{-7}	10^{-1} to 10^{-7}	5.00
		Cytotoxicity	--	No cytotoxicity	No cytotoxicity	
		Log_{10} $TCID_{50}$/carrier	--	≤ 0.50	≤ 0.50	
		Log Reduction	--	≥ 4.50	≥ 4.50	
516310-18	Hepatitis A Virus, Strain HM-175	Complete inactivation	--	10^{-1} to 10^{-8}	10^{-1} to 10^{-8}	6.50
		Cytotoxicity	--	No cytotoxicity	No cytotoxicity	
		Log_{10} $TCID_{50}$/carrier	--	≤ 0.50	≤ 0.50	
		Log Reduction	--	≥ 6.00	≥ 6.00	
516310-19	Herpes Simplex Virus Type 1, ATCC VR-733 Strain F (1)	Complete inactivation	--	10^{-1} to 10^{-8}	10^{-1} to 10^{-8}	6.25
		Cytotoxicity	--	No cytotoxicity	No cytotoxicity	
		Log_{10} $TCID_{50}$/carrier	--	≤ 0.50	≤ 0.50	
		Log Reduction	--	≥ 5.75	≥ 5.75	
516310-20	Herpes Simplex Virus Type 2, ATCC VR-734, Strain G	Complete inactivation	--	10^{-1} to 10^{-8}	10^{-1} to 10^{-8}	4.75
		Cytotoxicity	--	No cytotoxicity	No cytotoxicity	
		Log_{10} $TCID_{50}$/carrier	--	≤ 0.50	≤ 0.50	
		Log Reduction	--	≥ 4.25	≥ 4.25	
516310-21	Middle East Respiratory Syndrome Coronavirus (MERS-CoV) Strain EMC/2012 Source: BEI Resources (NR-44260)	Complete inactivation	--	10^{-2} to 10^{-7}	10^{-2} to 10^{-7}	5.35
		Cytotoxicity	--	No cytotoxicity	No cytotoxicity	
		Log_{10} $TCID_{50}$/carrier	--	≤ 1.10	≤ 1.10	
		Log Reduction	--	≥ 4.25	≥ 4.25	
516310-22	Murine Norovirus Strain S99	Complete inactivation	--	10^{-2} to 10^{-8}	10^{-2} to 10^{-8}	5.75
		Cytotoxicity	--	10^{-1}	10^{-1}	
		Log_{10} $TCID_{50}$/carrier	--	≤ 1.50	≤ 1.50	
		Log Reduction	--	≥ 4.25	≥ 4.25	
516310-23	Respiratory Syncytial Virus (RSV) ATCC VR-26, Strain Long	Complete inactivation	--	10^{-2} to 10^{-6}	10^{-2} to 10^{-6}	4.50
		Cytotoxicity	--	10^{-1}	10^{-1}	
		Log_{10} $TCID_{50}$/carrier	--	≤ 1.50	≤ 1.50	
		Log Reduction	--	≥ 3.00	≥ 3.00	

Virucidal Efficacy						
MRID	**Organism**	**Description**	**Results**			**Dried Virus Control (Log_{10} $TCID_{50}$/carrier)**
			Batch 18DEJ02	**Batch 18DEJ03**	**Batch 18DEJ04**	
Dilute 1/3 cup per gallon 100 ppm hard water, 5% soil load, 5-minute 30 seconds contact time						
516310-24	SARS-Associated Coronavirus, Strain: CDC 200300592; Source ZeptoMetrix/CDC	Complete inactivation	--	10^{-2} to 10^{-7}	10^{-2} to 10^{-7}	6.35
		Cytotoxicity	--	No cytotoxicity	No cytotoxicity	
		Log_{10} $TCID_{50}$/carrier	--	≤ 1.10	≤ 1.10	
		Log Reduction	--	≥ 5.25	≥ 5.25	
MRID	**Organism**	**Description**	**Results**			**Dried Virus Control (Log_{10} $TCID_{50}$/carrier)**
			--	**Batch 21LMP04**	**Batch 21LMP05**	
Dilute 1/3 cup per gallon 100 ppm hard water, 5% soil load, 5-minute 30 seconds contact time						
515569-01	SARS-Related Coronavirus-2 isolate hCoV19/England/204820464/2020#NR-54000);	Complete inactivation	--	10^{-1} to 10^{-6}	10^{-1} to 10^{-6}	5.00
		Cytotoxicity	--	No cytotoxicity	No cytotoxicity	
		Log_{10} $TCID_{50}$/carrier	--	≤ 0.50	≤ 0.50	
		Log Reduction	--	≥ 4.50	≥ 4.50	
	SARS-Related Coronavirus-2 isolate hCoV19/South Africa/KRISP-EC-K00532 l/2020 (BEI #NR-54008)	Complete inactivation	--	10^{-1} to 10^{-6}	10^{-1} to 10^{-6}	5.50
		Cytotoxicity	--	No cytotoxicity	No cytotoxicity	
		Log_{10} $TCID_{50}$/carrier	--	≤ 0.50	≤ 0.50	
		Log Reduction	--	≥ 5.00	≥ 5.00	
	SARS-Related Coronavirus-2 isolate USA/CA_CDC_5574/2020 (BEI #NR 54011)	Complete inactivation	--	10^{-1} to 10^{-6}	10^{-1} to 10^{-6}	5.00
		Cytotoxicity	--	No cytotoxicity	No cytotoxicity	
		Log_{10} $TCID_{50}$/carrier	--	≤ 0.50	≤ 0.50	
		Log Reduction	--	≥ 4.50	≥ 4.50	

*Dilution refers to the fold of dilution from the virus inoculum. Post neutralized sample was considered the 10^{-1} dilution.

V STUDY CONCLUSIONS

HARD, NON-POROUS SURFACE DISINFECTION								
MRID	**Claim**	**Surface Type**	**Application Method(s) and Dilution**	**Contact Time**	**Soil load**	**Diluent**	**Organism(s)**	**Data support tested conditions?**
516310-01 516310-02 516310-03	Disinfectant, bactericidal	Hard, non-porous surfaces	Dilutable liquid; 1/3 cup/gallon	5 minutes 30 seconds	5% FBS	100 ppm AOAC Hard Water	• *Pseudomonas aeruginosa* ATCC 15442	**Yes**
516310-04	Disinfectant, bactericidal	Hard, non-porous surfaces	Dilutable liquid; 1/3 cup/gallon	5 minutes 30 seconds	5% FBS	100 ppm AOAC Hard Water	• *Bordetella pertussis* ATCC 12743	**Yes**
516310-05	Disinfectant, bactericidal	Hard, non-porous surfaces	Dilutable liquid; 1/3 cup/gallon	5 minutes 30 seconds	5% FBS	100 ppm AOAC Hard Water	• *Campylobacter jejuni* ATCC 129428	**Yes**
516310-06	Disinfectant, bactericidal	Hard, non-porous surfaces	Dilutable liquid; 1/3 cup/gallon	5 minutes 30 seconds	5% FBS	100 ppm AOAC Hard Water	• *Listeria monocytogenes* ATCC 19111	**Yes**
516310-07	Disinfectant, bactericidal	Hard, non-porous surfaces	Dilutable liquid; 1/3 cup/gallon	5 minutes 30 seconds	5% FBS	100 ppm AOAC Hard Water	• Multi-Drug Resistant (MDR) *Acinetobacter baumanni* ATCC 19606	**Yes**
516310-08	Disinfectant, bactericidal	Hard, non-porous surfaces	Dilutable liquid; 1/3 cup/gallon	5 minutes 30 seconds	5% FBS	100 ppm AOAC Hard Water	• *Shigella dysenteria* ATCC 11835	**Yes**
516310-09	Disinfectant, bactericidal	Hard, non-porous surfaces	Dilutable liquid; 1/3 cup/gallon	6 minutes	5% FBS	100 ppm AOAC Hard Water	• *Streptococcus pneumoniae* ATCC 6305	**Yes**
516310-10	Disinfectant, bactericidal	Hard, non-porous surfaces	Dilutable liquid; 1/3 cup/gallon	5 minutes 30 seconds	5% FBS	100 ppm AOAC Hard Water	• Vancomycin Resistant *Enterococcus faecalis* ATCC 5129	**Yes**
516310-11	Disinfectant, bactericidal	Hard, non-porous surfaces	Dilutable liquid; 1/3 cup/gallon	5 minutes 30 seconds	5% FBS	100 ppm AOAC Hard Water	• *Vibrio cholerae* ATCC 23715	**Yes**
516310-12	Disinfectant, bactericidal	Hard, non-porous surfaces	Dilutable liquid; 1/3 cup/gallon	5 minutes 30 seconds	5% FBS	100 ppm AOAC Hard Water	• *Yersinia enterocolitica* ATCC 23715	**Yes**
516310-13	Disinfectant, fungicidal	Hard, non-porous surfaces	Dilutable liquid; 1/3 cup/gallon	5 minutes 30 seconds	5% FBS	100 ppm AOAC Hard Water	• *Candida albicans* ATCC 10231	**Yes**
516310-14	Disinfectant, fungicidal	Hard, non-porous surfaces	Dilutable liquid; 1/3 cup/gallon	5 minutes 30 seconds	5% FBS	100 ppm AOAC Hard Water	• *Trichophyton interdigitale* ATCC 9533	**Yes**
516310-15	Disinfectant, virucidal	Hard, non-porous surfaces	Dilutable liquid; 1/3 cup/gallon	5 minutes 30 seconds	5% FBS	100 ppm AOAC Hard Water	• Adenovirus Type 2, Strain: Adenoid 6 Source: ATCC VR-846	**Yes**
516310-16	Disinfectant, virucidal	Hard, non-porous surfaces	Dilutable liquid; 1/3 cup/gallon	5 minutes 30 seconds	5% FBS	100 ppm AOAC Hard Water	• Coxsackievirus type B ATCC VR-30, Strain Nancy	**Yes**
516310-17	Disinfectant, virucidal	Hard, non-porous surfaces	Dilutable liquid; 1/3 cup/gallon	5 minutes 30 seconds	5% FBS	100 ppm AOAC Hard Water	• Enterovirus type D68, ATCC VR-1825, Strain US/KY/14-18953	**Yes**
516310-18	Disinfectant, virucidal	Hard, non-porous surfaces	Dilutable liquid; 1/3 cup/gallon	5 minutes 30 seconds	5% FBS	100 ppm AOAC Hard Water	• Hepatitis A Virus, Strain HM-175	**Yes**
516310-19	Disinfectant, virucidal	Hard, non-porous surfaces	Dilutable liquid; 1/3 cup/gallon	5 minutes 30 seconds	5% FBS	100 ppm AOAC Hard Water	• Herpes Simplex Virus Type 1, ATCC VR-733 Strain F (1)	**Yes**
516310-20	Disinfectant, virucidal	Hard, non-porous surfaces	Dilutable liquid; 1/3 cup/gallon	5 minutes 30 seconds	5% FBS	100 ppm AOAC Hard Water	• Herpes Simplex Virus Type 2, ATCC VR-734, Strain G	**Yes**

HARD, NON-POROUS SURFACE DISINFECTION								
MRID	**Claim**	**Surface Type**	**Application Method(s) and Dilution**	**Contact Time**	**Soil load**	**Diluent**	**Organism(s)**	**Data support tested conditions?**
516310-21	Disinfectant, virucidal	Hard, non-porous surfaces	Dilutable liquid; 1/3 cup/gallon	5 minutes 30 seconds	5% FBS	100 ppm AOAC Hard Water	• Middle East Respiratory Syndrome Coronavirus (MERS-CoV) Strain EMC/ 2012 Source: BEI Resources (NR-44260)	**Yes**
516310-22	Disinfectant, virucidal	Hard, non-porous surfaces	Dilutable liquid; 1/3 cup/gallon	5 minutes 30 seconds	5% FBS	100 ppm AOAC Hard Water	• Murine Norovirus Strain S99	**Yes**
516310-23	Disinfectant, virucidal	Hard, non-porous surfaces	Dilutable liquid; 1/3 cup/gallon	5 minutes 30 seconds	5% FBS	100 ppm AOAC Hard Water	• Respiratory Syncytial Virus (RSV) ATCC VR-26, Strain Long	**Yes**
516310-24	Disinfectant, virucidal	Hard, non-porous surfaces	Dilutable liquid; 1/3 cup/gallon	5 minutes 30 seconds	5% FBS	100 ppm AOAC Hard Water	• SARS-Associated Coronavirus, Strain: CDC 200300592; Source ZeptoMetrix/CDC	**Yes**
515569-01	Disinfectant, virucidal	Hard, non-porous surfaces	Dilutable liquid; 1/3 cup/gallon	5 minutes 30 seconds	5% FBS	400 ppm AOAC Hard Water	• SARS-Related Coronavirus-2 isolate hCoV19/England/ 204820464/2020 (BEI #NR-54000); • SARS-Related Coronavirus-2 isolate hCoV19/South Africa/KRISP-EC-K00532 l/2020 (BEI #NR-54008) • SARS-Related Coronavirus-2 isolate USA/CA_CDC_5574/2020 (BEI #NR 54011)	**Yes**

LAUNDRY PRE-SOAK DISINFECTION								
MRID	**Product Tested (Review Date)**	**Claim**	**Surface Type**	**Application Method(s) and Dilution**	**Contact Time**	**Soil load**	**Organism(s)**	**Data support tested conditions?**
516310-01 516310-02 516310-03	5813-120 5813-121 (this review)	Disinfection, bactericidal	Hard, non-porous surfaces	Use-Dilution; 1/3 cup + 1 gallon of 100 ppm hard water	5 minutes 30 seconds	5% FBS	• *Pseudomonas aeruginosa* ATCC 15442	**Yes**
506322-07 506322-08 506322-09	5813-120 (5/1/2019)	Disinfection, bactericidal	Hard, non-porous surfaces	Use-Dilution; 1/3 cup + 1 gallon of 100 ppm hard water	5 minutes 30 seconds	5% FBS	• *Staphylococcus aureus* ATCC 6538	**Yes**
506322-10	5813-120 (5/1/2019)	Disinfection, bactericidal	Hard, non-porous surfaces	Use-Dilution; 1/3 cup + 1 gallon of 100 ppm hard water	5 minutes 30 seconds	5% FBS	• *Salmonella enterica* ATCC 10708	**Yes**
506322-12	5813-120 (5/1/2019)	Disinfection, bactericidal	Hard, non-porous surfaces	Use-Dilution; 1/3 cup + 1 gallon of 100 ppm hard water	6 minutes	5% FBS	• *Klebsiella aerogenes* (ATCC 13048) *(*previously known as *Enterobacter aerogenes)*	**Yes**

LAUNDRY PRE-SOAK DISINFECTION								
MRID	**Product Tested (Review Date)**	**Claim**	**Surface Type**	**Application Method(s) and Dilution**	**Contact Time**	**Soil load**	**Organism(s)**	**Data support tested conditions?**
506322-13	5813-120 (5/1/2019)	Disinfection, bactericidal	Hard, non-porous surfaces	Use-Dilution; 1/3 cup + 1 gallon of 100 ppm hard water	5 minutes 30 seconds	5% FBS	• Extended Spectrum Beta Lactamase (ESBL) producing *Escherichia coli* (ATCC BAA-196)	**Yes**
506322-17	5813-120 (5/1/2019)	Disinfection, virucidal	Hard, non-porous surfaces	Use-Dilution; 1/3 cup + 1 gallon of 100 ppm hard water	5 minutes 30 seconds	5% FBS	• 2009-H1N1 Influenza A Virus (Novel H1N1) (Strain A/NewMexico/4108/ 2009, CDC #2009712192)	**Yes**
506322-18	5813-120 (5/1/2019)	Disinfection, virucidal	Hard, non-porous surfaces	Use-Dilution; 1/3 cup + 1 gallon of 100 ppm hard water	5 minutes 30 seconds	5% FBS	• Avian Influenza A Virus (H3N2) (Avian Reassortant) (ATCC VR-2072) (Strain A; Washington; 897/80)	**Yes**
506322-19	5813-120 (5/1/2019)	Disinfection, virucidal	Hard, non-porous surfaces	Use-Dilution; 1/3 cup + 1 gallon of 100 ppm hard water	5 minutes 30 seconds	5% FBS	• Avian Influenza Virus (H7N9) (Strain wildtype A/Anhui/1/2013, CDC #2013759189)	**Yes**
506322-20	5813-120 (5/1/2019)	Disinfection, virucidal	Hard, non-porous surfaces	Use-Dilution; 1/3 cup + 1 gallon of 100 ppm hard water	5 minutes 30 seconds	5% FBS	• Avian Influenza Virus (H5N1) (Strain VNH5N1-PR8/CDC-RG #2006719965)	**Yes**
506322-21	5813-120 (5/1/2019)	Disinfection, virucidal	Hard, non-porous surfaces	Use-Dilution; 1/3 cup + 1 gallon of 100 ppm hard water	5 minutes 30 seconds	5% FBS	• Canine Influenza Virus (H3N8) (Strain A/Ca/NY/105913/08)	**Yes**
506322-22	5813-120 (5/1/2019)	Disinfection, virucidal	Hard, non-porous surfaces	Use-Dilution; 1/3 cup + 1 gallon of 100 ppm hard water	5 minutes 30 seconds	5% FBS	• Feline Calicivirus (surrogate for Norovirus) (ATCC VR-782) (Strain F-9)	**Yes**
506322-23	5813-120 (5/1/2019)	Disinfection, virucidal	Hard, non-porous surfaces	Use-Dilution; 1/3 cup + 1 gallon of 100 ppm hard water	5 minutes 30 seconds	5% FBS	• Human Coronavirus (ATCC VR-740 Strain 229-E)	**Yes**
506322-24	5813-120 (5/1/2019)	Disinfection, virucidal	Hard, non-porous surfaces	Use-Dilution; 1/3 cup + 1 gallon of 100 ppm hard water	5 minutes 30 seconds	5% FBS	• Influenza A Virus (Strain A/Hong Kong/8/68)	**Yes**
506322-25	5813-120 (5/1/2019)	Disinfection, virucidal	Hard, non-porous surfaces	Use-Dilution; 1/3 cup + 1 gallon of 100 ppm hard water	5 minutes 30 seconds	5% FBS	• Poliovirus Type 1 (Chat Strain, ATCC VR-1562)	**Yes**
506322-26	5813-120 (5/1/2019)	Disinfection, virucidal	Hard, non-porous surfaces	Use-Dilution; 1/3 cup + 1 gallon of 100 ppm hard water	5 minutes 30 seconds	5% FBS	• Rhinovirus Type 14 (ATCC VR-284) (Strain 1059)	**Yes**
506322-27	5813-120 (5/1/2019)	Disinfection, virucidal	Hard, non-porous surfaces	Use-Dilution; 1/3 cup + 1 gallon of 100 ppm hard water	5 minutes 30 seconds	5% FBS	• Bovine Viral Diarrhea Virus (BVDV) (Surrogate for Human Hepatitis C Virus) (Strain NADL)	**Yes**
506322-28	5813-120 (5/1/2019)	Disinfection, virucidal	Hard, non-porous surfaces	Use-Dilution; 1/3 cup + 1 gallon of 100 ppm hard water	5 minutes 30 seconds	5% FBS	• Measles Virus (ATCC VR-24) (Strain Edmonston)	**Yes**

LAUNDRY PRE-SOAK DISINFECTION								
MRID	**Product Tested (Review Date)**	**Claim**	**Surface Type**	**Application Method(s) and Dilution**	**Contact Time**	**Soil load**	**Organism(s)**	**Data support tested conditions?**
506322-29	5813-120 (5/1/2019)	Disinfection, virucidal	Hard, non-porous surfaces	Use-Dilution; 1/3 cup + 1 gallon of 100 ppm hard water	5 minutes 30 seconds	5% FBS	• Mumps Virus (ATCC VR-1438) (Strain Jones)	**Yes**
506322-30	5813-120 (5/1/2019)	Disinfection, virucidal	Hard, non-porous surfaces	Use-Dilution; 1/3 cup + 1 gallon of 100 ppm hard water	5 minutes 30 seconds	5% FBS	• Rotavirus (Strain SA-11)	**Yes**
509339-01	5813-120 (5/1/2020)	Disinfectant, bactericidal	Hard, non-porous surfaces	Dilutable liquid; 1/3 cup + 1 gallon of 100 ppm hard water	5 minutes 30 seconds	5% FBS	• *Legionella pneumophila* (ATCC 33153)	**Yes**
509339-02	5813-120 (5/1/2020)	Disinfectant, bactericidal	Hard, non-porous surfaces	Use-Dilution; 1/3 cup + 1 gallon of 100 ppm hard water	5 minutes 30 seconds	5% FBS	• *Streptococcus pyogenes* (ATCC 12344)	**Yes**
509339-04	5813-120 (5/1/2020)	Disinfectant, virucidal	Hard, non-porous surfaces	Use-Dilution; 1/3 cup + 1 gallon of 100 ppm hard water	5 minutes 30 seconds	5% FBS	• Cytomegalovirus (ATCC VR-538)	**Yes**
509339-05	5813-120 (5/1/2020)	Disinfectant, virucidal	Hard, non-porous surfaces	Use-Dilution; 1/3 cup + 1 gallon of 100 ppm hard water	5 minutes 30 seconds	5% FBS	• Duck Hepatitis B Virus (Human Hepatitis B Surrogate) (Strain Grimaud)	**Yes**
509339-07	5813-120 (5/1/2020)	Disinfectant, virucidal	Hard, non-porous surfaces	Use-Dilution; 1/3 cup + 1 gallon of 100 ppm hard water	5 minutes 30 seconds	5% FBS	• Human Immunodeficiency Virus Type 1 (Strain IIIB)	**Yes**
509339-08	5813-120 (5/1/2020)	Disinfectant, virucidal	Hard, non-porous surfaces	Use-Dilution; 1/3 cup + 1 gallon of 100 ppm hard water	5 minutes 30 seconds	5% FBS	• Influenza Virus Type B (ATCC VR-823) (Strain B/Hong Kong/5/72)	**Yes**
509339-09	5813-120 (5/1/2020)	Disinfectant, virucidal	Hard, non-porous surfaces	Use-Dilution; 1/3 cup + 1 gallon of 100 ppm hard water	5 minutes 30 seconds	5% FBS	• Parainfluenza Virus Type 3, ATCC VR-93, Strain C243	**Yes**
509339-10	5813-120 (5/1/2020)	Disinfectant, virucidal	Hard, non-porous surfaces	Use-Dilution; 1/3 cup + 1 gallon of 100 ppm hard water	5 minutes 30 seconds	5% FBS	• Rubella Virus (German Measles Virus), ATCC VR-1359, Strain RA27/3	**Yes**
512123-01	5813-120 5813-121 (9/15/2020)	Disinfectant, virucidal	Hard, non-porous surfaces	Use-Dilution; 1/3 cup + 1 gallon of 400 ppm hard water	5 minutes 30 seconds	5% FBS	• SARS-CoV-2 Virus [Strain USA-WA1/2020] [{SARS-related Coronavirus 2}]	**Yes**
515569-01	5813-120 5813-121 (this review)	Disinfectant, virucidal	Hard, non-porous surfaces	Use-Dilution; 1/3 cup + 1 gallon of 400 ppm hard water	5 minutes 30 seconds	5% FBS	• SARS-CoV-2 • Isolate hCoV19/England/204820464/2020 (BEI #NR-54000), • Isolate hCoV19/South Africa/KRISP-EC-K005321/2020 (BEI #NR-54008), • Isolate USA/CA_CDC_5574/2020 (BEI #NR-54011)];	**Yes**

LAUNDRY DISINFECTION								
MRID	**Product Tested**	**Clorox Bleach Resulting Test Concentration (ppm NaOCl)**	**CRB and CRB I Laundry Disinfection Dose**	**Corresponding concentration for CRB and CRB I at LCL**	**Dilution**	**Contact Time**	**Organism(s)**	**Data support tested conditions?**
43220903	5813-50	Batch 1: 147ppm Batch 2: 148ppm Batch 3: 146ppm	1 cup per 69L washer volume	195 ppm NaOCl	1:389	10 minutes	• *Staphylococcus aureus* ATCC 6538 • *Klebsiella pneumoniae* ATCC 4352 • *Pseudomonas aeruginosa* ATCC 15442	**No**, confirmatory testing data is required in order to bridge data from 5813-1 and 5813-50.
44838101	5813-1	Batch 1: 195ppm Batch 2: 194ppm	1 cup per 69L washer volume	195 ppm NaOCl	1:280	10 minutes	• Hepatitis A virus, strain HM-175 (Variant 18F of ATCC VR-1073)	**No**, confirmatory testing data is required in order to bridge data from 5813-1 and 5813-50.
44838102	5813-1	Batch 1: 195ppm Batch 2: 194ppm	1 cup per 69L washer volume	195 ppm NaOCl	1:280	10 minutes	• Influenza virus type A2 (Hong Kong) ATCC VR-544	**No**, confirmatory testing data is required in order to bridge data from 5813-1 and 5813-50.
44838103	5813-1	Batch 1: 195ppm Batch 2: 194ppm	1 cup per 69L washer volume	195 ppm NaOCl	1:280	10 minutes	• Rhinovirus type 37 ATTC VR-1147 • Rotavirus strain WA	**No**, confirmatory testing data is required in order to bridge data from 5813-1 and 5813-50.

VI LABEL COMMENTS

Label Date/Identification Number:

7/16/2021: CRB, EPA Reg. No. 5813-120
7/15/2021: CRB I, EPA Reg. No. 5813-121

1. The proposed labels claim that the following products,
   - CRB, EPA Reg. No. 5813-120
   - CRB I, EPA Reg. No. 5813-121

   when diluted 1/3 cup per gallon 100 ppm AOAC synthetic hard water is an effective bactericidal disinfectant against the following on visibly clean, hard, non-porous surfaces for a 5-minute 30-second contact time:

Pseudomonas aeruginosa (ATCC 15442)	MRID 516310-01 MRID 516310-02 MRID 516310-03
Bordetella pertussis ATCC12743	MRID 516310-04
Campylobacter jejuni ATCC 129428	MRID 516310-05
Listeria monocytogenes ATCC19111	MRID 516310-06
Multi-Drug Resistant (MDR) *Acinetobacter baumanni* ATCC 19606	MRID 516310-07
Shigella dysenteria ATCC 11835	MRID 516310-08
Vancomycin Resistant *Enterococcus faecalis* ATCC 51299	MRID 516310-10
Vibrio cholerae ATCC11623	MRID 516310-11
Yersinia enterocolitica ATCC 23715	MRID 516310-12

   These claims are **acceptable** as they are supported by the submitted data.

2. The proposed labels claim that the following products,
   - CRB, EPA Reg. No. 5813-120
   - CRB I, EPA Reg. No. 5813-121

   when diluted 1/3 cup per gallon 100 ppm AOAC synthetic hard water is an effective bactericidal disinfectant against the following on visibly clean, hard, non-porous surfaces for a 6-minute contact time:

Streptococcus pneumoniae ATCC 6305	MRID 516310-09

   These claims are **acceptable** as they are supported by the submitted data.

3. The proposed labels claim that the following products,
   - CRB, EPA Reg. No. 5813-120
   - CRB I, EPA Reg. No. 5813-121

   when diluted 1/3 cup per gallon 100 ppm AOAC synthetic hard water is an effective fungicidal disinfectant against the following on visibly clean, hard, non-porous surfaces for a 9-minute 30-second contact time:

Candida albicans ATCC 10231	MRID 516310-13
Trichophyton interdigitale ATCC 9533	MRID 516310-14

   These claims are **acceptable** as they are supported by the submitted data.

4. The proposed labels claim that the following products,
   - CRB, EPA Reg. No. 5813-120
   - CRB I, EPA Reg. No. 5813-121

when diluted 1/3 cup per gallon 100 ppm AOAC synthetic hard water is an effective virucidal disinfectant against the following on visibly clean, hard, non-porous surfaces for a 5-minute 30-second contact time:

Adenovirus Type 2, Strain: Adenoid 6 Source: ATCC VR-846	MRID 516310-15
Coxsackievirus Type B ATCC VR-1825, Strain Nancy	MRID 516310-16
Enterovirus Type D68, ATCC VR-1825, Strain US/KY/14-18953	MRID 516310-17
Hepatitis A Virus Strain HM-175	MRID 516310-18
Herpes Simplex Virus Type 1, ATCC VR-733 Strain F1	MRID 516310-19
Herpes Simplex Virus Type 2, ATCC VR-734, Strain G	MRID 516310-20
Middle East Respiratory Syndrome Coronavirus (MERS-CoV) Strain EMC/2012 Source: BEI Resources (NR-44260)	MRID 516310-21
Murine Norovirus Strain S99	MRID 516310-22
Respiratory Syncytial Virus (RSV) ATCC VR-26, Strain Long	MRID 516310-23
SARS-Associated Coronavirus, Strain: CDC 200300592. Source ZeptoMetrix/CDC	MRID 516310-24
SARS-CoV-2	MRID 515569-01

[Isolate hCoV19/~~England~~alpha/204820464/2020 (BEI #NR-54000)
Isolate hCoV19/~~South Africa~~beta/KRISP-EC-K005321/2020 (BEI #NR-54008)
Isolate ~~USA~~alpha/CA_CDC_5574/2020 (BEI #NR-54011)]

These claims are **acceptable** as they are supported by the submitted data.

5. The proposed labels claim that the following products,
   - CRB, EPA Reg. No. 5813-120
   - CRB I, EPA Reg. No. 5813-121

   when diluted 1/3 cup per gallon 100 ppm AOAC synthetic hard water is an effective laundry pre-soak disinfectant against the following for a 6-minute contact time:

Pseudomonas aeruginosa (ATCC 15442)	MRID 516310-01 MRID 516310-02 MRID 516310-03
Staphylococcus aureus ATCC 6538	MRID 506322-07 MRID 506322-08 MRID 506322-09
Salmonella enterica ATCC 10708	MRID 506322-10
Klebsiella aerogenes ATCC 13048	MRID 506322-12
Extended Spectrum Beta Lactamase (ESBL) producing *Escherichia coli* (ATCC BAA-196)	MRID 506322-13
2009-H1N1 Influenza A Virus (Novel H1N1) (Strain A/New Mexico /4108/2009, CDC #2009712192)	MRID 506322-17
Avian Influenza A Virus (H3N2) (Avian Reassortant) (ATCC VR-2072) (Strain A; Washington; 897/80)	MRID 506322-18
Avian Influenza Virus (H7N9) (Strain wildtype A/Anhui/1/2013, CDC #2013759189)	MRID 506322-19
Avian Influenza Virus (H5N1) (Strain VNH5N1-PR8/CDC-RG #2006719965)	MRID 506322-20
Canine Influenza Virus (H3N8) (Strain A/Ca/NY/105913/08)	MRID 506322-21
Feline Calicivirus (surrogate for Norovirus) (ATCC VR-782) (Strain F-9)	MRID 506322-22
Human Coronavirus (ATCC VR-740 Strain 229-E)	MRID 506322-23
Influenza A Virus (Strain A/Hong Kong/8/68)	MRID 506322-24
Poliovirus Type 1 (Chat Strain, ATCC VR-1562)	MRID 506322-25
Rhinovirus Type 14 (ATCC VR-284) (Strain 1059)	MRID 506322-26
Bovine Viral Diarrhea Virus (BVDV) (Surrogate for Human Hepatitis C Virus) (Strain NADL)	MRID 506322-27

Measles Virus (ATCC VR-24) (Strain Edmonston)	MRID 506322-28
Mumps Virus (ATCC VR-1438) (Strain Jones)	MRID 506322-29
Rotavirus (Strain SA-11) (ATCC VR-899)	MRID 506322-30
Legionella pneumophila ATCC 33153	MRID 509339-01
Streptococcus pyogenes ATCC12344	MRID 509339-02
Cytomegalovirus ATCC VR-538	MRID 509339-04
Duck Hepatitis B Virus (Human Hepatitis B Surrogate) (Strain Grimaud)	MRID 509339-05
Human Immunodeficiency Virus Type 1 (Strain IIIB)	MRID 509339-07
Influenza Virus Type B (ATCC VR-823) (Strain B/Hong Kong/5/72)	MRID 509339-08
Parainfluenza Virus Type ATCC VR-93	MRID 509339-09
Rubella Virus (German Measles Virus) (ATCC VR-1359) (Strain RA27/3)	MRID 509339-10
SARS-CoV-2 Virus [Strain USA-WA1/2020] [{SARS-related Coronavirus 2}]	MRID 512123-01
SARS-CoV-2	MRID 515569-01

[Isolate hCoV19/~~England~~alpha/204820464/2020 (BEI #NR-54000)
Isolate hCoV19/~~South Africa~~beta/KRISP-EC-K005321/2020 (BEI #NR-54008)
Isolate ~~USA~~alpha/CA_CDC_5574/2020 (BEI #NR-54011)]

These claims are **acceptable** as they are supported by the submitted and previously reviewed data (Efficacy reviews dated 5/1/2019, 4/3/2020 (Amended 5/1/2020) and 9/15/2020).

6. The proposed labels claim that the following products,
   - CRB, EPA Reg. No. 5813-120
   - CRB I, EPA Reg. No. 5813-121

   when diluted with a laundry disinfection dose of 1 cup per 69L washer volume is an effective laundry disinfectant against the following for a 10-minute contact time:

Staphylococcus aureus ATCC 6305	MRID 432209-03
*Klebsiella pneumonia*e ATCC 4352	MRID 432209-03
Pseudomonas aeruginosa ATCC 15442	MRID 432209-03
Hepatitis A virus, strain HM-175	MRID 448381-01
Influenza virus type A2 (Hong Kong) ATCC VR-544	MRID 448381-02
Rhinovirus Type 37 ATCC VR-1147	MRID 448381-03
Rotavirus (Strain WA)	MRID 448381-03

These claims are **not acceptable** as they are not supported by the cited data from 5813-1 and 5813-50. According to 810.2000 General Considerations for Testing Public Health Antimicrobial Pesticides Guidance for Efficacy testing, section (B)(7) confirmatory data may be required to support a new application or amendment for registration. Due to differences in inert ingredients in products 5813-1 and 5813-50, confirmatory data will be required to cite data for laundry disinfection claims for 5813-120 and 5813-121.

7. Make the following changes to the proposed labels (page numbers may vary – the page numbers below align with the label for CRB, EPA Reg. No. 5813-120, RC425043):

   a) Throughout the label,
      i. remove claim and directions for use for laundry disinfection.
      ii. mentions of COVID-19 virus should be qualified with the appropriate footnote to link COVID-19 to SARS-CoV-2.
      iii. remove mention of ‘attacks’, ‘fights’ and when related to public health microorganism.

iv. Terms such as “common” and “household” where associated with germs/bacteria/viruses/fungi should be qualified to link to the tested organisms as the agency has not defined these terms.
v. Remove brackets from footnotes as these should not be optional

b) On page 8 of the proposed label,
   i. revise instructions for “Food-contact [Work] Surfaces” and “Refrigerators, Freezers” to specify that surfaces remain visibly wet for the duration of the contact time.
   ii. Recommend that use directions for refrigerators and freezers specify in text that surfaces be allowed to come to room temperature prior to treatment, rather than by footnote to ensure clarity. Footnotes may be more appropriate for other labeling such as marketing claims or use site listings.

c) On pages 13-16 of the proposed label, for each set of public health use directions, revise “let stand” to “allow surface to remain visibly wet for”

d) On page 20 of the proposed label,
   i. under the heading of “List 5” remove “Laundry Disinfection”.
   ii. under the heading of “List 6” remove “Laundry Disinfection” and related organisms.

e) On page 22, qualify “Gets Rid of Germs” with “99.9%” to avoid implying enhanced efficacy

f) On page 23 of the proposed label,
   i. remove “kill most common viruses harmful to pets” or appropriately link to specific organisms.
   ii. qualify “make -or- create -or- mix your own disinfecting -and/or- [32oz] [bleach] spray [solution]” with when diluted according to use directions .
   iii. Remove “Pandemic 2009” from “Pandemic 2009 H1N1 influenza A virus” as this is not part of the virus nomenclature.

g) On page 24, remove “streptocidal”. This is not a common label claim and may be confusing for end users.

h) On page 26 of the proposed label, recommend removal of the statement “Bleach starts and ends with [table] salt and water” as this is too vague.

i) On page 31 of the proposed label,
   i. appliances that should be brought to room temperature before product application, such as ovens and stove[top]s, should indicate “allow surfaces to reach room temperature prior to treatment”.
   ii. remove “sidewalks” and other surfaces that are not hard, non-porous from list of use sites under “hard, non-porous surfaces”.

j) On page 32 of the proposed label, remove “sealed brick”, “sealed patio stone” and “sealed stucco”. Sealant helps these surfaces become less porous but not nonporous. As these surfaces are exposed to the elements, there’s likely more variability in the effectiveness of sealant for these surfaces.

k) On pages 34-38 and 45 ensure that each set of public health use instructions are consistent with earlier parts of the label and specify that treated surfaces remain visibly wet for the duration of the contact time.

l) On page 45-47 of the proposed label, include language per DIS/TSS-18 (https://archive.epa.gov/pesticides/oppad001/web/html/dis-18.html) when there are directions to use a disinfectant on farm premises.